IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	))))	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF DEPOSITION AND SUBPOENA OF WATSON LABORATORIES, INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Janssen") will take the deposition upon oral examination of Watson Laboratories, Inc. at the offices of Ashby & Geddes, 222 Delaware Avenue, 17th Floor, Wilmington, Delaware 19801 beginning at 9:00 A.M. on June 20, 2006.

NOTICE IS FURTHER GIVEN THAT the deposition will be recorded stenographically through instant visual display of testimony (real-time), by certified shorthand reporter and notary public or such other person authorized to administer oaths under the laws of the United States, and shall continue from day to day until completed. This deposition will be videotaped.

NOTICE IS FURTHER GIVEN THAT pursuant to the Federal Rules of Civil Procedure, Janssen will serve upon Watson Laboratories, Inc. a Subpoena in a Civil Case. Attached hereto as Exhibit A is a true and correct copy of that Subpoena.

ASHBY & GEDDES

/s/ Tiffany Geyer Lydon

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
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222 Delaware Avenue, 17th Floor
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Attorneys for Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc.

Dated: June 2, 2006

170127.1

EXHIBIT A

A088 Subpoena in a Civil Case

Issued by the

United States District Court

DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION

SUBPOENA IN A CIVIL CASE

Case Number:[1] C.A. No. 05-356-KAJ (consolidated)
(District of Delaware)

TO: Watson Laboratories, Inc.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. Please See Schedule A Attached

PLACE OF DEPOSITION Recording Method: By stenographer and videotape	DATE AND TIME
Ashby & Geddes, 222 Delaware Avenue, 17th Floor, Wilmington, Delaware 19899	June 20, 2006; 9:00 AM EST

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects): Please See Schedule B Attached

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE AND TIME
Attorney for Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc.	June 2, 2006
Tiffany Geyer Lydon	
ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER Tiffany Geyer Lydon, Ashby & Geddes 222 Delaware Avenue, 17th Floor Wilmington, DE 19899 Tel: 302-654-1888	

(See Rule 45, Federal Rules of Civil Procedure, Parts C&D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

_____
ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C&D

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(2)(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance,

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden

(3)(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

SCHEDULE A

DEFINITIONS

1. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

2. As used herein, "ANDA" shall mean Abbreviated New Drug Application Number 77-767.

3. As used herein, "Plaintiffs" refers to Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc., either individually or collectively.

4. As used herein, "You," "Your," or "Yours," shall mean Watson Laboratories, Inc., Watson Laboratories, Inc.'s corporate predecessors and past or present parents, subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents, employees and any individuals or entities that at any time have acted or purported to act on behalf of Watson Laboratories, Inc. or its successors.

TOPICS

1. The notice You sent to Plaintiffs on August 26, 2005, attached hereto as Exhibit 1.

2. Your patent certification regarding the '318 patent in connection with ANDA No. 77-767.

EXHIBIT 1

WATSON Laboratories, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc.

ABBREVIATED NEW DRUG APPLICATION 77-767
OFFER OF CONFIDENTIAL ACCESS
PURSUANT TO 21 U.S.C. § 355(j)(5)(C)(i)(III)

WHEREAS WATSON Laboratories, Inc. ("Watson") has provided notice to Janssen Pharmaceutica Products, L.P. and Janssen Pharmaceutica N.V. (hereinafter "Recipients"), that Watson submitted to the U.S. Food and Drug Administration ("FDA") Abbreviated New Drug Application 77-767 for 4, 8, and 12 mg Galantamine Hydrobromide Tablets (referred to hereinafter in whole or in part as the "ANDA"), containing a Paragraph IV certification with respect to U.S. Patent Nos. 6,099,863 and 6,358,527 (the "Listed Patents"), which are listed in the FDA Publication, "Approved Drug Products with Therapeutic Equivalence Evaluations"; and

WHEREAS this document constitutes Watson's Offer of Confidential Access to that ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) which provides:

> The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement;

and

WHEREAS Watson desires to offer to provide Recipients confidential access to the ANDA subject to restrictions as to persons entitled access to, and on the use and disposition of, the ANDA; and

WHEREAS this document accompanies Watson's Notice and Detailed Statement under 21 U.S.C. § 355(j)(2)(B) with respect to the Listed Patents;

NOW, THEREFORE:

1. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), and subject to the restrictions contained in Section 2 below, Watson hereby provides Recipients this Offer of Confidential Access ("Offer") for the sole purpose of determining whether to bring an action referred to in 21 U.S.C. § 355(j)(5)(B)(iii) with respect to the Listed Patents.

2. This Offer is subject to the following restrictions as to persons entitled to access and the use and disposition of any information accessed:

A. **Persons Entitled to Access:** Persons entitled to access ("Authorized Evaluators") under this Offer of Confidential Access are restricted to: (i) outside counsel engaged or employed by Recipients to represent them and the staff of such outside counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel, provided that such outside counsel has been identified to Watson in writing; (ii) no more than two (2) in-house counsel and the staff of such in-house counsel, including paralegal, secretarial and clerical personnel who are engaged in assisting such counsel; and (iii) independent consultants and experts assisting in the evaluation of possible infringement of the Listed Patents and any employees and assistants under the control of such consultant or expert.

B. **Materials Accessible by Authorized Evaluators:** A copy of the ANDA, redacted to remove information of no relevance to any issue of patent infringement, will be provided for use by Authorized Evaluators.

C. **Use of the ANDA and Information in the ANDA:**

(1) The ANDA and all information contained therein or derived therefrom may be used for the sole and limited purpose of evaluating possible infringement of the Listed Patents and for no other purpose.

(2) Authorized Evaluators shall not disclose any information contained in or derived from the ANDA or any notes, analyses, studies or other documents to the extent that they reflect any information in the ANDA, to any person other than person entitled to access under subsection A.

(3) Notwithstanding the provisions of subsections 2(C)(1) and 2(C)(2) above, Authorized Evaluators shall be permitted to advise Recipients whether or not to bring suit alleging infringement of the Listed Patents; provided, however, that the information in the ANDA is not thereby disclosed.

D. **Disposition of the Information in the ANDA:**

(1) Recipients agree that if they do not file suit against Watson alleging infringement of the Listed Patents within forty-five (45) days of receipt of the Notice and Detailed Statement (the "45-day period"), which this offer accompanies, Recipients shall cause Authorized Evaluators within thirty (30) days after the expiration of the 45-day period, to destroy or return to Watson the portions of the ANDA provided, and all notes, analyses, studies or other documents to the extent that they contain information in the ANDA, and Recipients shall notify Watson that this has been done.

(2) Recipients agree that if any Recipient files suit against Watson alleging infringement of the Listed Patents within the 45-day period:

(a) While the litigation is pending, the portions of the ANDA provided and all notes, analyses, studies or other documents to the

extent that they contain information in the ANDA, shall be treated as information under the highest level of confidentiality under any protective order entered in the action brought against Watson. Until such a protective order is entered, subsection 2(C)(2) above continues to apply.

(b) Recipients shall cause Authorized Evaluators to destroy or return to Watson the portions of the ANDA provided and all notes, analyses, studies or other documents prepared to the extent that they contain information in the ANDA, within thirty (30) days after the final determination of the action brought against Watson.

(3) Notwithstanding the provisions of subsections 2(D)(1) and 2(D)(2) above, each outside law firm authorized to have access pursuant to subsection 2(A)(i) shall be permitted to retain one copy of the portions of the ANDA provided and each note, analysis, study or other document to the extent that they contain information in the ANDA.

E. **Accidental Disclosure:** Should information contained in the ANDA be disclosed, inadvertently or otherwise, Recipients shall, at their earliest opportunity, by and through Authorized Evaluators, contact Watson and identify:

(1) what has been disclosed;

(2) the individuals to whom such information has been disclosed; and

(3) steps taken by Recipients and Authorized Evaluators to ensure the information in the ANDA is not further disseminated.

3. Recipients acknowledge that violation of any provision of this Offer will cause irreparable injury to Watson, and that an adequate legal remedy does not exist. Watson, therefore, shall have the right, in addition to any other remedies available at law or in equity, to obtain from a court of competent jurisdiction an injunction to prohibit Recipients from violating the terms of this Offer. Recipients agree that in such an action Watson is entitled to recover any and all damages, costs and expenses, including, but not limited to, all reasonable attorneys' fees, professional fees and court costs.

4. Should any provision set forth in this Offer be found by a court of competent jurisdiction to be illegal, unconstitutional or unenforceable, the remaining provisions shall continue in full force and effect.

5. Nothing contained herein shall be construed as a grant of any license or other right to use the information in the ANDA except for the purpose expressly stated herein.

6. When accepted by Recipient, this document shall constitute the entire agreement of the parties with respect to the subject matter herein and may not be amended or modified except in writing executed by all of the parties.

7. Recipients may request access to the ANDA by executing one copy of this Offer where indicated and returning the executed copy to the Watson authorized agent, below,

within the 45-day period. Thereupon, the terms contained in this document shall be considered an enforceable contract between Watson and the Recipients.

WATSON Laboratories, Inc.
By its authorized agent:

Ernest Leyle, Ph.D.

Watson Laboratories, Inc.

Date: 16 Aug '05

Recipient
By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Company: _____

Date: _____

WATSON Laboratories, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc.

Watson Laboratories, Inc.'s Detailed Statement Of The Factual And Legal Bases For Its Opinion That U.S. Patent Nos. 6,099,863 And 6,358,527 Are Invalid, Unenforceable Or Not Infringed By The Manufacture, Use Or Sale Of Watson's 4, 8, And 12 mg Galantamine Hydrobromide Tablets

This is the detailed statement of Watson Pharmaceuticals, Inc. ("Watson"), pursuant to Section 505(j)(2)(B)(ii) of the Food and Drug Act (codified at 21 U.S.C. § 355(j)(2)(B)(ii)), and 21 C.F.R. § 314.95(c), of its factual and legal bases for its opinion that U.S. Patents Nos. 6,099,863 ("the '863 patent"), and 6,358,527 ("the '527 patent"), are invalid, unenforceable, or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use or sale of Watson's 4, 8, and 12 mg galantamine hydrobromide tablets ("Watson's tablets"), for which this detailed statement is submitted. The bases for Watson's opinion follow.

I. The '863 Patent

The '863 patent, entitled *Fast-Dissolving Galanthamine Hydrobromide Tablet*, issued August 8, 2000, from application S/N 09/202,187 (filed December 9, 1998), which is the national stage application of PCT/EP97/02986 (filed June 6, 1997), which claims foreign priority to EP96.201676 (filed June 14, 1996). Assigned on its face to Janssen Pharmaceutica N.V. (Beerse, Belgium), the '863 patent lists Paul Marie Victor Gillis and Valentin Florent Victor De Condé as inventors, and contains ten (10) claims, one (1) of which is independent. Claim 1 recites:

> 1. A tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Claims 2, 3, 5 and 7 depend directly from claim 1. Claims 4 and 10 depend from claim 3. Claim 6 depends from claim 5, claim 8 from claim 7, and claim 9 depends from claim 8. The dependent claims further define: the disintegrant (claim 2); the carrier (claim 3); the glidant (claim 4); the weight percent of the components (claims 5-6); the film coating (claims 7-8); the weight percent of the film coating (claim 9); and, the process to make the tablet of claim 3 (claim 10). The process of claim 10 recites:

> 10. A process of preparing a tablet according to claim 3 comprising the steps of:
> (i) dry blending the active ingredient, the disintegrant and the optional glidant with the diluent;
> (ii) optionally mixing the lubricant with the mixture obtained in step (i);
> (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and
> (iv). Optionally film-coating the tablet obtained in step (iii).

II. The '527 Patent

The '527 patent, entitled *Fast-Dissolving Galanthamine Hydrobromide Tablet*, issued March 19, 2002, from application S/N 09/585,122 (filed June 1, 2000), which is a continuation of application S/N 09/202,187 (filed December 9, 1998, now the '863 patent), which is the national stage application of PCT/EP97/02986 (filed June 6, 1997), which claims foreign priority to EP96.201676 (filed June 14, 1996). Assigned on its face to Janssen Pharmaceutica N.V. (Beerse, Belgium), the '863 patent lists Paul Marie Victor Gillis and Valentin Florent Victor De Condé as inventors, and contains six (6) claims, of which two (2) are independent. Independent claims 1 and 6 recite:

> 1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.
>
> * * * *
>
> 6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-link polymer disintegrant and an optional glidant with a diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

Claims 2, 4 and 5 depend directly from claim 1, whereas claim 3 depends from claim 2. The dependent claims are directed to treating: dementia (claim 2); Alzheimer's dementia (claim 3); mania (claim 4); and, nicotine dependence (claim 5).

III. Watson's Tablets Will Not Infringe Any Valid Claim Of The '863 Or '527 Patents

To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir.), *cert. denied*, 116 S. Ct. 515 (1995). If the independent claims are not infringed there is no infringement of the claims depending from them. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Infringement under the doctrine of equivalents requires that the accused article or composition contain every element of the claims, either literally or as an equivalent. *Unique Concepts v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991). This doctrine cannot erase "meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement." *Pennwalt Corp. v. Durand-Wayland, Inc.* 833 F.2d 931, 935 (Fed. Cir. 1987) (*en banc*), *cert. denied*, 485 U.S. 1009 (1988) (quoting *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987).

Prosecution history estoppel limits the doctrine of equivalents. As noted in *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1460 (Fed. Cir. 1998) (*en banc*), "[p]rosecution history estoppel provides a legal limitation on the application of the doctrine of equivalents by excluding from the range of equivalents subject matter surrendered during prosecution of the application for the patent."

A. The '863 Patent Claims Are Not Infringed By Watson's Tablets, Either Literally Or Under The Doctrine Of Equivalents

1. Claim Construction

Two claim terms are expressly defined in the '863 patent in a manner contrary to customary usage. The patentees specifically define the word "tablet" and the term "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)." "Tablet" is defined as having "a dissolution of at least 80% after 30 minutes (Q=80% after 30')(USP 23,<711> Dissolution, pp 1791-1793, Apparatus 2 (paddle, 50 rpm))." ('863 patent, Col. 3, lines 7-9).

Watson Laboratories, Inc.'s Detailed Statement Of The Factual And Legal Bases For Its Opinion That U.S. Patent Nos. 6,099,863 And 6,358,527 Are Invalid, Unenforceable Or Not Infringed By The Manufacture, Use Or Sale Of Watson's 4, 8, And 12 mg Galantamine Hydrobromide Tablets

The term "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)" is defined as "commercially available as Microcelac™" ('863 patent, Col. 3, lines 19-23). Microcelac™ is a spray-dried compound containing 75% lactose monohydrate and 25% microcrystalline cellulose as a one-body excipient.[1] Thus, the term "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)," means a one-body excipient containing a spray-dried combination of 75% lactose monohydrate and 25% microcrystalline cellulose.

2. Watson's Tablets Will Not Literally Infringe The '863 Patent Claims

Watson's tablets will not literally infringe any claim of the '863 patent. Claim 1 is directed to a tablet that "comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent." This spray-dried mixture is a one-body spray-dried excipient containing 75% lactose monohydrate and 25% microcrystalline cellulose, which Watson's tablets will not contain. Watson's tablets use lactose monohydrate and microcrystalline cellulose as separate and distinct excipients.

In addition, the ratio of lactose monohydrate to microcrystalline cellulose claimed in the '863 patent is 3:1, while in Watson's tablets it is 0.64 :1. Thus, Watson's tablets will not literally infringe independent claim 1 of the '863 patent.

Nor will Watson's tablets literally infringe dependent product-by-process claim 10. Claim 10 depends from dependent claim 3, which requires that the tablet of claim 1 comprise a glidant and a lubricant. Since Watson tablets will not infringe the tablet of claim 1, the product made by the process of claim 10 is not literally infringed by Watson's tablets either.

Moreover, Watson's tablets will not literally infringe the remainder of dependent claims 2-9. This is because Watson's tablets do not contain the critical feature of the alleged invention – a diluent comprising a one-body excipient containing spray-dried lactose monohydrate and microcrystalline cellulose.

3. Watson's Tablets Will Not Infringe The '863 Patent Claims Under The Doctrine of Equivalents

Watson's tablets will not infringe any claim of the '863 patent under the doctrine of equivalents. The '863 patent requires the critical feature of a one-body excipient of spray-dried lactose monohydrate and microcrystalline cellulose, which Watson's tablets do not contain.

The '863 patentees specifically disclaim formulations containing lactose monohydrate and microcrystalline cellulose as separate and distinct excipients.

> Initial experiments started out using either lactose anhydrous or lactose monohydrate as diluent, and either powdered cellulose or microcrystalline cellulose as disintegrant (see tablet formulations F1 and F2 in the Experimental Part). A particular problem which occurred during feeding the dry blend into the tablet press for direct compression, was to have a variable composition. In addition, the tablets formulations F1 and F2 did not comply at Stage 1 with the dissolution specification of

[1] *See* http://www.meggle-pharma.de/en/products/uebersicht/microcelac100/ for product information on Microcelac™.

> Q-80% after 30'. In order to solve the percieved *[sic]* problems, the diluent was substituted for a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25), commercially available as Microcelac™. '863 patent, Col. 3, lines 14-23.

Example 2 of the '863 patent discloses a formulation (F2) containing lactose monohydrate and microcrystalline cellulose as individual excipients. However, the specification specifically states that this formulation does not meet the requirements of the "tablet" of claim 1. "Neither of F1 or f2 [sic] comply at stage 1 with the dissolution specification Q=80% at 30% [sic] minutes." ('863 patent, Col. 8, lines 24-25).

The prosecution history also shows that the claims do not cover formulations containing lactose monohydrate and microcrystalline cellulose as individual excipients. In conjunction with submission of the national stage application, the patentees submitted the PCT International Preliminary Examination Report ("International Report"). The International Report states that

> [t]he subject-matter of claims 1 and 10 differs from [the prior art] in that the mixture of lactose and microcrystalline cellulose is spray-dried and in that the ratio of the lactose monohydrate to microcrystalline cellulose is 75:25. (International Report, dated July 14, 1998, at page 4).

The '863 patent is equal in scope to the PCT. Further, in entering the Notice of Allowance the examiner specifically stated that the scope of the '863 patent is limited to a one-body excipient of spray-dried lactose monohydrate and microcrystalline cellulose.

Based on disclaimers in the specification and statements made during prosecution, Watson's tablets will not infringe claim 1 of the '863 patent under the doctrine of equivalents. The patentees explicitly placed galantamine formulations containing lactose monohydrate and microcrystalline cellulose as separate and distinct excipients in the public domain. Thus, a one-body excipient is not equivalent to separate and distinct excipients.

Dependent claims 2-9 also require the excipient of a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). Since Watson's tablets do not contain an equivalent excipient, they will not infringe claims 2-9 under the doctrine of equivalents.

Watson's tablets will not infringe dependent process claim 10, which is directed to preparing the galantamine tablet of claim 1. Thus, claim 10 requires the tablet have a dissolution of at least 80% after 30 minutes (Q=80% after 30')(USP 23,<711> Dissolution, pp 1791-1793, Apparatus 2 (paddle, 50 rpm))." ('863 patent, Col. 3, lines 7-9). According to the specification, however, formulations containing separate lactose monohydrate and microcrystalline cellulose excipients do not meet this requirement. (*See*, '863 patent, Col. 3, lines 10-19). Consequently, whether or not a court views process recitations as claim limitations, Watson's tablets are not equivalent to those of the '863 patent.

B. The '527 Patent Claims Are Not Infringed By Watson's Tablets, Either Literally Or Under The Doctrine Of Equivalents

1. Claim Construction

As described above, the '527 patent is a continuation of the '863 patent. Consequently, the two claim terms expressly defined in the '527 patent in a manner contrary to customary usage are the same as in the '863 patent. The patentees

specifically define the word "tablet" and the term "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)," and the meanings are discussed in connection with the '863 patent, above.

2. There Is No Direct Infringement Of The '527 Patent Claims

Watson will not directly infringe any of claims 1-5 of the '527 patent under § 271(a), since it will not administer its tablets to a patient.

Nor will Watson's tablets infringe claim 6 of the '527 patent, either literally or under the doctrine of equivalents. Regardless of whether the process recitations are considered claim limitations, Watson's tablets will not literally infringe claim 6 since it requires a tablet having a dissolution of at least 80% after 30 minutes. According to the patent, formulations containing separate lactose monohydrate and microcrystalline cellulose excipients do not meet this dissolution requirement, and thus, Watson's tablets will not literally infringe claim 6.

Example 2 of the '527 patent discloses the F2 formulation containing lactose monohydrate and microcrystalline cellulose as individual excipients, which the patent says does not meet the requirements of the "tablet" claimed in claim 1. Since the '527 patent disclaims formulations with lactose monohydrate and microcrystalline cellulose as separate and distinct excipients because they do not meet the required dissolution, Watson's tablets will not infringe claim 6 of the '527 patent under the doctrine of equivalents.

Furthermore, during prosecution and to overcome an enablement rejection, the applicants amended claim 6 to specifically include the "spray-dried mixture of lactose monohydrate and microcrystalline cellulose". (*See*, Amendment, dated August 22, 2001). The amendment limited the scope of the claim to the spray-dried mixture. Thus, the patentees are estopped from asserting that any diluent is equivalent to the "spray-dried mixture of lactose monohydrate and microcrystalline cellulose."

3. Watson's Tablets Would Neither Induce Nor Contribute To The Infringement Of The '527 Patent Claims

Section § 271(b) provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." Furthermore, it is not an infringing act to sell, or offer to sell in the U.S. a composition which can be used in practicing a patented process or method, if the composition is a staple article or commodity of commerce suitable for substantial non-infringing use. Title 35 U.S.C. § 271(c). Liability for inducing or contributing to infringement requires a direct infringement. *See, BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 981 (Fed. Cir. 1993).

Watson's tablets will not induce or contribute to the infringement of method-of-use claims 1-5. The '527 patent specifically states that formulations containing lactose monohydrate and microcrystalline cellulose as separate and distinct excipients do not meet the dissolution requirement of claim 1. Since Watson's tablets contain separate lactose monohydrate and microcrystalline cellulose excipients, administration of Watson's tablets would not directly infringe claim 1. Without a direct infringement, there is no induced or contributory infringement.

Nor would Watson infringe the remaining dependent method of use claims, claims 2-5. All of the dependent claims require the administration of the tablet recited in claim 1. One administering Watson's tablets would not directly infringe these claims, and consequently, there is no induced or contributory infringement.

IV. Conclusion

For the reasons stated above, all claims of U.S. Pats. Nos. 6,099,863 and 6,358,527 are invalid, unenforceable or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use of sale of Watson's 4, 8 and 12 mg galantamine hydrobromide tablets. Watson reserves the right to develop additional grounds, reasons and authorities that any or all of the claims of these U.S. Patents are invalid, unenforceable, or not infringed.

Ernest Levy, M.D.

Watson Pharmaceuticals, Inc.

26 Aug '05

Date

Watson Laboratories, Inc.'s Detailed Statement Of The Factual And Legal Bases For Its Opinion That U.S. Patent Nos. 6,099,863 And 6,358,527 Are Invalid, Unenforceable Or Not Infringed By The Manufacture, Use Or Sale Of Watson's 4, 8, And 12 mg Galantamine Hydrobromide Tablets

August 26, 2005

VIA CERTIFIED MAIL **RETURN RECEIPT REQUESTED** NDA owner: Janssen Pharmaceutica Products, L.P. 1125 Trenton-Harbourton Rd Titusville, New Jersey 08360-0200	**VIA CERTIFIED MAIL** **RETURN RECEIPT REQUESTED** Representative of Patent Owner: Janssen Pharmaceutica N.V. Turnoutseweg 30 B-2340 Beerse Country Belgium

Re: Patent Certification Notice – U.S. Patent Nos. 6,099,863 and 6,358,527
Watson's 4, 8, and 12 mg galantamine hydrobromide tablets
Watson Laboratories, Inc.'s ANDA 77-767

To Whom It May Concern:

The purpose of this communication is to provide the notice and information required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii) (sections 505(j)(2)(B)(i) and (ii) of the Food, Drug and Cosmetic Act) that Watson Laboratories, Inc. ("Watson"), a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California 92880-2882, has submitted an ANDA for this drug product which contains the required bioavailability and/or bioequivalence data and Paragraph IV certification with respect to U.S. Patent Nos. 6,099,863 and 6,358,527.

A detailed statement of the factual and legal bases for Watson's position regarding these patents is provided herein. Watson reserves the right to assert additional grounds, reasons and authorities for its position that the aforesaid patents are invalid, unenforceable, or will not be infringed.

An Offer of Confidential Access to Watson's ANDA 77-767, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), accompanies this notice as a separate enclosure.

Sincerely,

Ernest Lengle, Ph.D.
Executive Director, Regulatory Affairs

Enclosures: Watson Laboratories, Inc.'s Detailed Statement Of The Factual And Legal Bases That U.S. Patent Nos. 6,099,863 and 6,358,527 Are Invalid, Unenforceable Or Not Infringed

Watson Laboratories, Inc.'s Offer of Confidential Access to ANDA 77-767.

CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of June, 2006, the attached **NOTICE OF DEPOSITION AND SUBPOENA OF WATSON LABORATORIES, INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45** was served upon the below-named counsel of record at the address and in the manner indicated:

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